K103473

MAY 13 2011

510(k) Summary:

Submitter's Name and Address:

ZOLL Medical Corporation
269 Mill Road
Chelmsford, MA 01824-4105
(978) 421-9655

Contact Person:

Charles W. Kolifrath

(978) 421-9786

Date Summary Prepared:

November 23, 2010

Device:

RescueNet ePCR

Classification:

Classification Product Code:

21 CFR 870.2450. Display, Cathode Ray Tube, Medical. Product code: DXJ. Device Class: 2.

Secondary Product Code:

Software, Transmission and Storage, Patient Data. Product code: NSX. Device Class: Not Classified.

Description:

The proposed RescueNet ePCR is a software-only product. RescueNet ePCR is a medical data collection system used to collect, store and print patient data that is entered by a user (caregiver), or captured from specified medical devices, and is integrated into a patient care report (patient electronic medical record). RescueNet ePCR is non-alarming software that runs on a variety of commercial off-the-shelf hardware.

Intended Use:

RescueNet ePCR is intended for the collection, storage and printing of patient data that is entered by a user (caregiver), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record). RescueNet ePCR is intended for use by qualified medical personnel

providing direct patient care in the pre-hospital environment to document the care provided. RescueNet ePCR is indicated for use by health care providers whenever there is a need for generation of a patient record.

Substantial Equivalence:

The features and functions of the proposed RescueNet ePCR are substantially equivalent to the corresponding features and functions of the Philips Medical Systems IntelliVue Clinical Information Portfolio (K100272, cleared for use on 4/14/2010).

Comparison of Technological Characteristics

RescueNet ePCR features and functions are similar to the corresponding features and functions of the indicated predicate device. Both RescueNet ePCR and the indicated predicate device are software-only products intended for the collection and storage of patient data, including data that is entered by a user (caregiver) and data collected from other medical devices. Both RescueNet ePCR and the indicated predicate device are indicated for use by health care providers whenever there is a need for generation of a patient record. No new issues of safety or effectiveness are raised by this premarket notification.

Performance Testing:

Extensive performance testing ensures that RescueNet ePCR performs as well as the indicated predicate device and meets all of its functional requirements and performance specifications.

Conclusion

Performance testing of RescueNet ePCR demonstrates that its features and functions are substantially equivalent to the corresponding features and functions of the indicated commercially distributed predicate device with regard to performance, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 13 2011

Mr. Charles W. Kolifrath
Regulatory Affairs Manager
Zoll Medical Corporation
269 Mill Road
Chelmsford, Massachusetts 01824

Re: K103473
Trade/Device Name: RescueNet ePCR
Regulation Number: 21 CFR 870.2450
Regulation Name: Medical Cathode-ray Tube Display
Regulatory Class: II
Product Code: DXJ, NSX
Dated: May 6, 2011
Received: May9, 2011

Dear Mr. Kolifrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 – INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: **RescueNet ePCR**

Intended Use:

RescueNet ePCR is intended for the collection, storage and printing of patient data that is entered by a user (caregiver), or captured from specified medical devices, and integrated into a patient care report (patient electronic medical record). RescueNet ePCR is intended for use by qualified medical personnel providing direct patient care in the pre-hospital environment to document the care provided. RescueNet ePCR is indicated for use by health care providers whenever there is a need for generation of a patient record.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Wesley Cox for RZC 5/13/2011

Division Sign-Off)

Division of Anesthesiology, General Hospital

fection Control, Dental Devices

10(k) Number: K103473